The following corrections or additions to the January 2004 list were published in the Federal Register in April 2004.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 140-338

This supplemental application provides for revised susceptibility information for equine pathogens listed in the clinical microbiology section of the labeling (package insert).

Trade Name:	Naxcel® Sterile Powder
Ingredients:	Ceftiofur
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	February 27, 2004
Species:	Horse
Status:	Prescription only

21CFR 522.313

NADA Number: 141-216

This supplemental application provides for the speciation of adult small strongyles in product labeling.

Trade Name:	Quest® Plus Gel
Ingredients:	Moxidectin, praziquantel
Sponsor:	Fort Dodge Animal Health, Division of Wyeth
Approval Date:	March 17, 2004
Status:	Over-the-counter
Route:	Oral
Species:	Horses and ponies
Drug Form:	Gel
Concentration:	20 milligrams moxidectin and 125 milligrams praziquantel per milliliter
Indications:	For the treatment and control of the following stages of gastrointestinal parasites of horses and ponies six months of age and older which will not to be used for food: **Large strongyles**: *Strongylus vulgaris* (adult and L4/L5 arterial stages), *Strongylus edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), *Triodontophorus serratus* (adults) **Small strongyles** (adults): *Cyathostomum spp*. including *C. catinatum*, *C. pateratum*; *Cylicocyclus spp*. including *C. insigne*, *C. leptostomum, C. nassatus; Cylicostephanus spp*. including *C.calicatus, C. goldi, C. longibursatus*, *C. minutis; Coronocyclus spp.,* including *C. coronatus, C. labiatus, C. labratus*; *Gyalocephalus capitatus*; undifferentiated luminal larvae **Encysted cyathostomes**: late L3 and L4 mucosal cyathostome larvae **Ascarids**: *Parascaris equorum* (adults and L4 larval stages) **Pinworms**: *Oxyuris equi* (adults and L4 larval stages) **Hairworms**: *Trichostrongylus axei* (adults) **Large-mouth stomach worms**: *Habronema muscae* (adults) **Horse stomach bots**: *Gasterophilus intestinalis* (2nd and 3rd instars), *G. nasalis* (3rd instars) **Tapeworms**: *Anoplocephala perfoliata* (adults) One dose also suppresses strongyle egg production for 84 days.
Patent Number:	4,916,154 Expiration date: April 10, 2007

21CFR 520.1453

Suitability Petition Action

Number:	04P-0130/CP1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug amoxicillin which differs from the pioneer product, Amoxi-Tabs®, Pfizer Inc., NADA 055-078 and NADA 055-081 by the following characteristic(s): The generic product will have a different strength (concentration) from the pioneer.
Action:	Filed on March 16, 2004.

Number:	04P-0167/CP1
Sponsor:	First Priority, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristic(s): The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.86 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.
Action:	Filed on April 8, 2004.

Number:	04P-0175/CP1
Sponsor:	Intervet, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristic(s): The generic product will have a change in strength (concentration) from the pioneer.
Action:	Filed on April 14, 2004.

Number:	04P-0167/WDL1
Sponsor:	First Priority, Inc.
Petition:	Request permission to withdraw petition to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristic(s): The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.86 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.
Action:	Acknowledged on April 26, 2004.

Technical Amendments

The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the approved salts of injectable furosemide. This action is being taken to improve the accuracy of the regulations. FDA has found that the animal drug regulations do not correctly identify the monoethanolamine salt of furosemide sponsored by Boehringer Ingelheim Vetmedica, Inc., and approved under NADA 127-034 and NADA 131-538. This error occurred with the approval of NADA 127-034 (49 FR 26715, June 29, 1984). This document amends the regulations in 21 CFR 522.1010 to correct this error.

The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the approved pre-slaughter withdrawal period in cattle following use of a penicillin G procaine injectable suspension. This action is being taken to improve the accuracy of the regulations. FDA has found that the animal drug regulations do not reflect the pre-slaughter withdrawal period in cattle for Penicillin G Procaine Aqueous Suspension sponsored by G.C. Hanford Manufacturing Co. and approved under NADA 065-493. This error was introduced into the regulations when sections for certain penicillin-containing products were re-codified (57 FR 37318, August 18, 1992). At this time, the regulations are being amended in 21 CFR 522.1696b to correct this error.

Amendment to Regulations for Food Additives Permitted in Feed and Drinking Water in Animals

The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of natamycin in broiler chicken feeds. Natamycin will be added to broiler chicken feed at a level of 11 parts per million (ppm) to retard the growth of *Aspergillus parasiticus* in the feed, for up to 14 days. This action is in response to a food additive petition filed by Arkion Life Sciences of Wilmington, DE. This rule is effective April 13, 2004, and 21CFR 573.685 is added to reflect this action.